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Terms	Documents
L1 and human cell	0

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L14	L13 same hyaluronidase	1	L14
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L12	(peripher$ blood monon$ cell$)	3526	L12
L11	(peripher$ blood mon$ cell$)	67	L11
L10	L1 same (peripheral) same (hyaluronidase)	0	L10
L9	L8 and hyaluronidase	1	L9
L8	L1 and peripheral	1	L8
L7	L1 and peripheral bllod mononuclear	0	L7
L6	L1 and human host cells	0	L6
L5	L1 and pmbcs	0	L5

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L4	L1 nan pmbcs	0	L4
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Use of **Human Cell Lines**

UVA Policy on the Use of Human Cell Lines

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Introduction

Human cell lines are commonly used in biomedical research, yet appropriate biosafety requirements for handling **human cell lines** are often subject to debate within the scientific community. In order to clarify the University's position on this matter, the Institutional Biosafety Committee has created the following policy.

Background

In 1991, the Occupational Safety and Health Administration (OSHA) issued the Bloodborne Pathogens (BBP) Standard to protect employees who have occupational exposure to human blood or other potentially infectious materials. While human blood, most body fluids, unfixed human tissues and organs were clearly included within the scope and application of the standard, the inclusion of **human cell lines** was ambiguous.

In 1994, OSHA issued an interpretation of the applicability of the BBP Standard towards **human cell lines**. According to the interpretation, **human cell lines** are considered to be potentially infectious and within the scope of the BBP Standard unless the specific cell line has been characterized to be free of hepatitis viruses, **HIV**, Epstein-Barr virus, papilloma viruses and other recognized bloodborne pathogens.[1] In alignment with this interpretation, the American Type Culture Collection (ATCC) recommends that all **human cell lines** be accorded the same level of biosafety consideration as a line known to carry **HIV**.[2] Moreover, the Fourth Edition of the CDC publication, *Biosafety in*

Microbiological and Biomedical Laboratories (BMBL), recommends that human and other primate cells should be handled using Biosafety Level 2 (BSL2) practices and containment.[3]

In consideration of the aforementioned regulatory interpretation and consensus guidelines and other factors, the UVA Institutional Biosafety Committee has adopted the following policy in regards to the use of **human cell lines**.

Policy

All cell and organ cultures of human origin, including well established cell lines, shall be handled in accordance with the OSHA Bloodborne Pathogens Standard and under Biosafety Level 2 (BSL2) containment.

References

1. OSHA Letter of Interpretation, URL: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=21519 VIEW URL
2. American Type Culture Collection Frequently Asked Questions, URL: http://www.atcc.org/TechnicalInfo/faqCellBiology.cfm#Q53 VIEW URL
3. Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, URL: http://www.bmbl.od.nih.gov/ VIEW URL

Adopted by unanimous vote of the Institutional Biosafety Committee (IBC), December 2003.

Marie-Louise Hammarskjold, IBC Chair

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EXPOSURE CONTROL PLAN

Appendix D: Application of the Exposure Control Plan to Human Cell Cultures

The provisions of the MSU Exposure Control Plan provide protection to employees who have occupational exposure to human blood or other potentially infectious materials (OPIM). Established human cell lines[1] which are characterized[2] as free of contamination from human hepatitis viruses, human immunodeficiency viruses, and other recognized bloodborne pathogens, are not to be considered as OPIM and are not covered by the bloodborne pathogens standard and the Exposure Control Plan.

Established human or animal cell lines that are potentially infected or contaminated with bloodborne pathogens, are covered by the provisions of the Exposure Control Plan.

The final judgment for making the determination if human or animal cell lines in culture are free of bloodborne pathogens will be made by the Biological Safety Officer at MSU and/or the Institutional Biosafety Committee (IBC) in consultation with the Principal Investigator (PI), in accordance with the requirements of the bloodborne pathogen standard. Documentation that such cell lines are not OPIM should be on file with the PI for MIOSHA review.

All primary human cell explants and *in vitro* passages of human tissue explant cultures (human cell strains[3]) must be regarded as containing bloodborne pathogens and are subject to Universal Precautions and the requirements of the ECP. Non-transformed, human cell strains characterized by documented, reasonable laboratory testing, to be free of HIV, hepatitis viruses, or other bloodborne pathogens may be exempted from the ECP requirements. However, tissue explants or subsequent cultures derived from human subjects known to carry bloodborne pathogens (e.g., HIV, HBV), or deliberately infected with bloodborne pathogens, must be handled in accordance with the bloodborne pathogens standard and the MSU ECP. The same applies for animal tissues and explants or cell lines contaminated by deliberate infection with bloodborne pathogens.

Definitions

[1] Human cell lines are defined as *in vitro* or animal passage (e.g., nude mouse) cultures or human cells that fulfill traditional requirements of a cell line designation. That is:

- immortalized cells;

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- cultures transformed by spontaneous mutation;
- cultures transformed by natural or laboratory infection with an immortalizing agent (e.g., Epstein-Barr Virus (EBV)).

Human cell lines may be adulterated with laboratory pathogens introduced by cultivation with other cell cultures, or cells may be physically contaminated by other cultures handled in the same lab. Cells should be documented to be pure cells and shown to be free of bloodborne pathogens in order to be exempted from the ECP requirements.

[2] Characterization of human cells, for exclusion from compliance with the bloodborne pathogen standard, must include (1) screening of the cell lines or strains for viruses characterized as bloodborne pathogens (e.g., HIV, HBV, EBV), and (2) determining that the cells are not capable of propagating such viruses. Most cell lines are screened only for human mycoplasmas and are determined to be free of bacterial and mycotic contaminants. Testing to identify latent viruses capable of infecting humans such as Herpesviruses (e.g., EBV), or papilloma members of the Papovirus group, etc. may include:

- antigenic screening for viral or agent markers;
- co-cultivation with various indicator cells that allow contaminants to grow;
- using molecular techniques (polymerase chain reaction or nucleic acid hybridization).

Cell lines obtained from commercial vendors or other sources documented as free of human bloodborne pathogens and protected by the employer from environmental contamination may be excluded from the bloodborne pathogens standard.

[3] Human cell strains are cells propagated *in vitro* from primary explants of human tissue or body fluids which have finite lifetime (non-transformed) in tissue cultures for 20-70 passages. Human cell strains must be handled as potential biohazards unless characterized by documented testing to be free of bloodborne pathogens.

Appendix D: Biohazardous Spill Response Procedure ▶

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